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SUMMARY

This was a for-cause inspection of a manufacturer of class III implantable contraceptive device for women. FDA foreign inspection of the firm's contract manufacturer (b) (4) found that (b) (4) The sole product of Conceptus (b) (4) (b) (4) I conducted this inspection pursuant to CP 7382.845 under PACs 82845G and 81011, as part of SAN-DO's FY '11 workplan for medical devices as FACTS Assignment #1246754.

Previous inspection on 7/9-11/2008 covered CAPA and Design Controls. No significant observations were made and no FDA 483 (Inspectional Observations) was issued.

Current inspection on 12/8-14/2010, 12/17-21/2010, and 1/4-6/2011 covered all major quality subsystems. During this inspection, I found that the firm was not reporting complaints of their product (a metal coil) being seen radiographically in the patient's abdominal cavity. I found that the firm did not have a risk analysis for coils being in the abdominal cavity. I also found that the firm did not open a CAPA when they became aware of their contract manufacturer (b) (4)

(b) (4) listed these observations on an FDA 483 that I issued to the firm's president at the close of the inspection.

The firm opened a CAPA for their contractor's nonconformance, and Mr. Henry V. Bishop, Quality Manager, promised to add coil in the abdominal cavity to their risk analysis. Firm officials said that they do not believe that complaints of injuries that are not directly resulting from their product and asymptomatic coils in the abdominal cavity should not be reported.

I collected two documentary samples: DOC444332, documenting the shipment of the firm's product from their contract manufacturer's (b) (4) to storage for distribution in (b) (4) (b) (4) verified and acknowledged by Mr. Henry V. Bishop, Quality Manager; and DOC444333, documenting the receipt of complaints of injuries occurring during the procedure for their product and their product being located in the abdominal cavity, verified and acknowledged by Mr. Edward C. Yu, Vice President Clinical Research and Regulatory Affairs.

ADMINISTRATIVE DATA

Inspected firm:	Conceptus, Inc.
Location:	331 E. Evelyn Ave. Mountain View, CA 94041
Phone:	650-962-4000
FAX:	650-691-4737
Mailing address:	331 E. Evelyn Ave. Mountain View, CA 94041
Dates of inspection:	12/8/2010, 12/9/2010, 12/10/2010, 12/13/2010, 12/14/2010, 12/17/2010, 12/20/2010, 12/21/2010, 1/4/2011, 1/5/2011, 1/6/2011
Days in the facility:	11
Participants:	Timothy C. Grome, Investigator

On Dec. 8, 2010 I presented my credentials and then issued an FDA 482 (Notice of Inspection, Att. 1) to Mr. Mark M. Sieczkarek, President & CEO of Conceptus, Inc. I issued another FDA 482 (Att. 2) to Mark M. Sieczkarek on Jan. 4, 2011 after a break in the inspection at more than one week. On Jan. 6, 2010 I issued an FDA 483 to Mark M. Sieczkarek (Att. 3). I amended the FDA 483 (Att. 4) deleting the reference to (b) (4) (b) (4) based on documents shown to me by firm personnel at the close-out meeting. Because of a technical problem with TurboEIR, I hand wrote the annotations to the FDA 483.

HISTORY

G. Robert McCarthy, Senior Director of Operations, told me that Conceptus, Inc. is a public corporation. There have been no significant changes to the corporate structure since the previous inspection in 2008. The Mountain View, CA location employs approximately employees. Hours of operations are from

Henry V. Bishop, Quality Manager informed me that the firm He said that this year the firm had a planned By Dec. 16, 2010 Mr. Bishop told me that could complete the inspection. On Dec. 21, 2010 when I told Mr. Bishop that I would need another two to four days to complete the inspection, he requested that I postpone the inspection until Jan. 5, 2011.

All correspondences to this firm should be made to:

Mark M. Sieczkarek, President and CEO
Conceptus, Inc.
331 E. Evelyn Ave.
Mountain View, CA 94041
(650) 962-4000

This firm has never had any regulatory actions recommended as the result of previous inspections. Inspections on 9/21-22/05 and 7/9-11/08 were classified NAI. Inspections on 7/8-11/02 and 6/25-7/9/03 were classified VAI for failure to analyze all sources of quality information for corrective and preventive actions for failure to follow their procedures for control of non-conforming material.

INTERSTATE COMMERCE

Conceptus, Inc. no longer manufactures its own product. All of the Essure305 contraceptive device kits are manufactured by sterilization, and stored for distribution at As per Mr. G. Robert McCarthy, Senior Director of Operations, the Mr. Henry V. Bishop, Quality Manager, told me that until % of Conceptus's products were manufactured Since then no products were being received by Conceptus I collected DOC444332 with an affidavit of Henry V. Bishop, who explained to me that Conceptus takes ownership of the assembled, pre-sterilized device kits Conceptus ships After sterilization the products are sent where

they are held for distribution to the final customer through (b) (4) DOC444332 documents the sale and shipment of (b) (4)

JURISDICTION

Conceptus, Inc. sells only one product the Essure305 permanent birth control system. The Essure was approved as PMA P020014 on 11/4/2002. The latest supplement S029 was approved 4/6/2010. The current model of Essure is ESS 305. Mr. Henry V. Bishop, Quality Manager told me that all devices of the previous model, ESS205, have passed their expiration dates. The Essure is (b) (4) sterilized packaged in kits of two catheter-coils each. Each kit contains labeling, and the catheter with the coil attached at the end of a placement wire. All labeling is included DOC444333.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

I did not pre-announce this inspection because it was a for-cause inspection. During this inspection I had contact with the following people:

Mark M. Sieczkarek, President and CEO was present at the opening and close-out meetings. I issued him the FDA 482 on Dec. 8, 2010, and on Jan. 4, 2011, and I issued to him the FDA 483 on Jan. 6, 2011. After I issued the FDA 482, he directed me to subordinates and excused himself from the inspection.

All firm personnel identified Mark M. Sieczkarek, President and CEO as the most responsible person in charge. He accepted the FDA 482 forms and the FDA 483. After I issued the form he excused himself and delegated his employees to discuss the particular items. After I annotated the FDA 483 I had to look for him at the firm in order to official give him the annotated FDA 483.

Edward C. Yu, Vice President Clinical Research and Regulatory Affairs is responsible for FDA submissions including 510(k)s and Medical Device Reports (MDRs). He reports directly to Mark M. Sieczkarek, President and CEO. He was present at the opening and close-out meetings, and for part of the inspection as he provided information on complaints and Medical Device Reporting. He provided me with copies of documents that supported the firm's decisions for MDRs. On Jan. 6, 2011 he signed an affidavit identifying product complaints (DOC444333).

Henry V. Bishop, Quality Manager identified himself and was identified as the management representative. He has responsibility for the application of the Quality System as it applies to CAPA and Design Controls and the oversight of contract processors. He reports to G. Robert McCarthy, Sr. Dir. of Operations.

During this inspection Mr. Bishop was my primary firm contact throughout the inspection. He was present with me throughout the inspection except when he was personally retrieving requested records or documents. He either provided me with requested records and documents or he directed his assistant to do so. On Jan. 5, 2011 he signed an affidavit identifying records showing interstate shipment of a lot of Essure (DOC444332).

G. Robert McCarthy, Senior Director of Operations was present at the opening and close out meetings. He is responsible for the over sight of contract manufacturers and sterilizers. He provided

information on the activities of the firm's contract manufacturers. He reports to Gregory E. Lichtwardt, Executive Vice President, Operations, Chief Financial Officer.

(b) (4), (b) (6), (b) (7)(C) was present at the opening and close-out meetings. He works for Henry V. Bishop in quality. He was present for the inspection, assisting Henry Bishop on 12/8-9/10 and on 1/4/11.

(b) (4), (b) (6), (b) (7)(C) was present for the inspection assisting Henry Bishop on 12/10 to 12/21/10 and on 1/5/11 and at the close out meeting. He works for Henry V. Bishop in quality.

(b) (4), (b) (6), (b) (7)(C) was interviewed on 12/20/2010 concerning his conversations with the contract manufacturer about (b) (4) (b) (4) He reports to Henry V. Bishop.

Michael G. Reddick, Product Surveillance Manager was present at the close-out meeting. He reports to Edward C. Yu.

FIRM'S TRAINING PROGRAM

I did not review the firm's employee training program.

MANUFACTURING/DESIGN OPERATIONS

Corrective and Preventive Actions: For my review of the firm's CAPA subsystem I looked at complaints and Non-Conforming Material Reviews. Mr. Henry V. Bishop, Quality Manager provided me with a copy of Corrective and Preventive Actions (CAPA) SOP-00935 Rev. U (Exhibit #1). He also provided me with the other SOPs: Non-Conforming Material Review SOP-00383 Rev. AA, and Product Return, Complaint Handling, and Reporting SOP-1630 Rev. AC (Exhibit #2) I requested to review a random 11 out of 14 CAPAs from 2010 (b) (4) (b) (4) (b) (4) (b) (6), (b) (7)(C) provided me with the files for 11 CAPAs. I found no exception observations with 10 of the 11 that I reviewed.

To follow up on the product failure noted at (b) (4) requested to see all CAPA activities concerning that failure: CAPA 0014 was opened on 10/25/10 for detachment failures noted during lot release of (b) (4) ESS305 (Exhibit #3). That CAPA had a blank in the box for preliminary action taken and for root cause analysis. On 12/21/10 Henry Bishop gave me (b) (4) with additional information in a printout of e-mails between Conceptus and (b) (4) (Exhibit #4). That Corrective Action Form says in the (b) (4) (b) (4) An attached letter (Page 9) (b) (4) (b) (4) (b) (4) I asked Henry Bishop if Conceptus had opened a corrective action about (b) (4) handling of the (b) (4) and the (b) (4) Mr. Bishop told me that all issues

(b) (4) were documented in CAPA 0014. On 12/20/2010 he told me that the (b) (4) would be covered under CAPA 0014 and the specific (b) (4) (b) (4) CAPA. That CAPA was opened in response to (b) (4) (Exhibit #5) (See FDA 483 Observation #4)

Design Controls: Since the last inspection the firm has not developed any new products. I reviewed the latest Henry V. Bishop, Quality Manager provided me with a copy of Risk Analysis Design FMEA (b) (4) Exhibit #6). I looked at this document in respect to the firm not reporting as MDRs complaints in which the coil had migrated into the abdominal cavity. Although there is a reference to perforations as a possible effect of the failure mode for the coil being too stiff, perforation itself and the possible coil in the abdominal cavity is not analyzed as a failure mode. (See Objectionable Conditions #3)

I reviewed the latest PMA supplements: P020014/S20 Real Time Supplement Dry Flow Valved Introducer Changes and Addition of (b) (4) Bond 7/22/08 (Amendment #1) which included Validation testing, Addition of (b) (4) 9/5/08 (Amendment #2), Changes to Delivery Wire Holder 9/5/08 (Amendment #3), P020014/S21 Delivery Wire Holder Release Band for detachment timing change 9/9/08 including (b) (4) (b) (4) ' for (b) (4) (b) (4) (b) (4)

To follow up on the product failure that led to this for-cause inspection, I requested documentation on all re-design activities concerning difficulty to deploy wire. Henry Bishop told me that (b) (4) (b) (4) the firm that supplies delivery wires to (b) (4) changed its process. Mr. Bishop gave me a copy of (b) (4) Corrective Action Request (b) (4) (Exhibit #7). That document states that (b) (4) (b) (4) (b) (4)

Management Controls: I reviewed the documents Management Review SOP-01104 Rev. T, and Internal Audit Procedure SOP-00415 Rev. AB. I reviewed the records sign-in sheet for the (b) (4) Management Review for (b) (4) I looked at the Internal Audit schedule for 2010. The last (b) (4) I found no objectionable conditions in the firm's management controls.

Production and Processing Controls: During this inspection I found no evidence that the firm was distributing lots that had failed testing for deployment force. I toured the firm's receiving areas. I observed the boxes of Essure that were being held in quarantine. I counted all the boxes, and compared my count with the number of product listed in (b) (4) I counted (b) (4) According to (b) (4) (Exhibit #5) there are a total of (b) (4) lots that have the disposition (b) (4) lots were held for retesting. (b) (4) lots passed testing. Mr. Bishop told me that those (b) (4) lots which passed were distributed in (b) (4) At the time of this

inspection these devices were being held at Conceptus, Inc. in Mountain View, CA in the quarantine area. These lots are [redacted] Henry Bishop provided me with a printout of 3.6.6 Inventory Detail by Location (Exhibit #9). This record is dated 12/8/2010. It shows the [redacted] ots listed in [redacted] and give a total o[redacted] units. The shipping boxes are packed [redacted] counted [redacted] boxes. The inventory accounts for all the boxes with partial counts for units removed for testing.

I covered the firm's control over its contract manufacturers and suppliers. At the time of this inspection, Conceptus was not receiving product from [redacted] in [redacted] He said that [redacted] Henry V. Bishop, Quality Manager provided me a copy of CAPA #0014 (Exhibit #3) [redacted] This CAPA does not document the plan for, [redacted] Mr. Bishop provided me with the [redacted] for Conceptus Essure ESS305 Document No.: [redacted] (Exhibit #8). This [redacted] See FDA 483 Observation #4). [redacted]

MANUFACTURING CODES

According to G. Robert McCarthy, Senior Director of Operations, Conceptus, Inc. has its contract manufacturers assign lot numbers. [redacted] Some lot numbers of devices from that contract manufacturer include [redacted] uses an [redacted] number some lots are [redacted]

COMPLAINTS

My inspection of the complaint system of Conceptus Inc. found that the firm was not reporting complaints of loose micro-insert coils in the peritoneal or abdomino-pelvic cavity (See FDA483 Observation #2). Some placement procedures have a perforation of the fallopian tubes. In some of these cases the micro-insert coil will migrate through the perforation in the tube and will be found on x-ray to be outside the female reproductive tract in the peritoneal cavity. Such cases will be reported as MDR by the firm if the patient is complaining of pain and a second procedure is required to remove the coil. However, the firm will not report such complaints if an abdominal located coil is removed during a laparoscopic tubal ligation performed because of failure of the Essure procedure.

Henry V. Bishop, Quality Manager provided me with a copy of Product Return, Complaint Handling, and Reporting SOP-1630 Rev. AC (Exhibit #2), Work Instruction WI-03303 Medical Device Vigilance (MDV) Reporting (Exhibit #10), and Work Instruction WI-03306 MDR Processing (Exhibit #11). He told me that complaints are kept in a computer database called [redacted] gave me a CD-ROM labeled "COMPLAINTS & MDR'S" with two Excel files: [redacted] and "[redacted]" with an Excel spreadsheet with all of the complaints opened since Jan. 1, 2008 there were 16,581 complaint from 1/1/08 until 12/6/10 listed. There were 182 MDRs reported in the same time period. The original spreadsheet for all complaints did not have a detailed description of the event. Henry Bishop gave me a more detailed complaint spreadsheet named '[redacted]' on a CD-ROM labeled '[redacted]' that starts at 7/20/2010 and goes to 12/10/2010. That spreadsheet that a total of 2,752 complaints. From the detailed spreadsheet I reviewed all 15 complaints for detachment difficulty of any kind.

I looked at the complaints for perforation during the procedure on th[redacted] database. I noted that none of the perforation complaints were reported as MDRs. I spoke with Edward C. Yu, Vice President Clinical Research and Regulatory Affairs, about perforation complaints. Mr. Yu gave me a copy of Correspondence between Conceptus and FDA concerning PMA P020014/R4/A4 March 30, 2004.

Because of the firm's communication with CDRH concerning complaints of perforation of the fallopian tubes and uteri, I changed my focus on the coil being found in the abdominal cavity (See FDA 483 Observations #1 and #2). When I returned to the firm on 1/4/2011 I requested an update to the complaint list[redacted] me a printout form the complaint database List of all[redacted] (complaints) from 12/8/2010 to 1/4/2011. In that list I found two complaints of coils in the abdominal cavity; one with patient pain and a planned removal to treat that pain that was not classified as MDR reportable (See FDA 483 Observations #1 and #2)

RECALL PROCEDURES

Henry V. Bishop, Quality Manager gave me a copy of the firm's Product Recall SOP, SOP 01045 (Exhibit #12). Mr. Bishop told me that the firm has not had a recall since the last inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, the following complaints from July 12, 2010 to Dec. 10, 2010 both report a bowel perforation that occurred during the procedure to place the firm's product:

1 (b) (4) incident and aware date of 11/3/2010: Perforation from scope; patient taken to hospital for exploratory laparoscopy. Resolution notes on 12/21/2010 states patient had bowel perforation with some hemorrhage. Patient had a hysterectomy.

2 (b) (4) incident and aware date of 11/16/2010: When doctor attempted to place second device, she used graspers to locate the ostium. She perforated the patients bowel.

In both complaints the firm's device did not directly cause the injury, but the procedure for use required the use of an hysteroscope and visualization of the tubal ostium. There were 41 complaints of perforation from July 12, 2010 to Dec. 10, 2010 the above two complaints were the only two of the 41 that involved perforation of the bowel. The other complaints were for uterus or fallopian tubes.

There was one complaint that was not for a perforation but for which a CT scan showed that the insert was in two pieces with one of the pieces outside of the tube between the uterus and the bowel:

3 (b) (4) incident date 11/05/2010, aware date 12/16/2010: Patient reported pain immediately following the procedure. Essure procedure done on 11/5/10 Performed a CT scan which revealed device was in 2 pieces; proximal part was in isthemal portion; distal between uterus and bowel.Physician plans laparoscopic removal tomorrow and tubal ligation.

Annotation: Promised to correct by Jan.15, 2011
Reference: 21 CFR 803.50(a)(1)

Supporting Evidence and Relevance: The annotation is only for (b) (4) Ed Yu told me on Jan. 5, 2011 that Conceptus, Inc. has decided to report this complaint as an MDR. I collected all three complaint files as DOC444333 with (b) (4) Att. #2), (b) (4) Att. #3), and (b) (4) (Att. #8 (b) (4) (DOC444333, Att. #2) and (b) (4) DOC444333, Att. #3) both were complaints involving a perforation or suspected perforation of the bowel. Both of these complaints involved an instrument that is not manufacturer by or for Conceptus, Inc. The instruments involved were not specifically called for in the Essure Instructions for Use (DOC 444332, Att. 14 (b) (4) he perforation was caused by the hysteroscope that was used to visualize the opening of the fallopian tube as instructed by the Instructions for use (DOC444332, Att. 14).

Conceptus has reported complaints in which the coil was found outside of the fallopian tube in the abdominal cavity, when there was a report of pain for which the coil is surgically or laparoscopically

removed. (b) (4) incident date 11/05/2010, initially reported that one of the coils was seen in two pieces, one of the pieces between the uterus and the bowel, and the patient was complaining of pain. The initial report was that surgery to remove the coil was being planned.

(b) (4), (b) (6), (b) (7)(c) gave me a copy of the updated file fo (b) (4) on Jan. 6, 2011 (Exhibit #13). The update (page 7) showed that the coil seen in the abdominal cavity was in one piece. Laparoscopic removal was not performed until 12/18/2010 (2 days after the initial report). Edward C. Yu told me that Conceptus would be filing an MDR fo (b) (4) The annotation only applies to this complaint.

Discussion with Management: On Jan. 5, 2011 Mr. Yu told me about the decision to report (b) (4) (b) (4) ased on the updated information. I said that the information that the firm had on 12/16/2010, when the complaint first was received by Conceptus, to make a decision to report. Because the firm was reporting this complaint I annotated the Observation as promised to correct. Mr. Yu told me that (b) (4) would not be reported because the devices that were responsible for the injuries were not made by or for Conceptus.

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the firm received complaints that a perforation had occurred with the coil micro-insert being seen radiographically outside of the Fallopian Tube in the abdominal cavity:

1 (b) (4) incident and aware date 10/01/2010: perforation 2 HSGs showed device was located in the peritoneum. The micro-insert was removed during a laparoscopic tubal ligation.

2. (b) (4) ncident date 10/05/2010, aware date 10/08/2010: Perforation; 1 micro-insert is in the peritoneal cavity. Essure was placed in June 2010 patient is asymptomatic.

3. (b) (4) incident date 5/11/2010, aware date 10/21/2010: Perforation observed on HSG. Essure procedure done 5/11/10. HSG shows device is outside the tube on the left side in the peritoneal cavity.

4. (b) (4) incident date 10/26/2010, aware date 10/26/2010: Perforation; on HSG micro-insert observed in the peritoneal cavity.

5. (b) (4) ncident date 09/01/2010, aware date 12/10/2010: Perforation: micro-insert located outside the tube in the cul-de-sac. Essure done on 09/01/10; no HSG done 12/09/10. Patient is asymptomatic.

During the time period of July 12, 2010 to January 4, 2011 there were 45 complaints for perforation. Two for perforation of bowel, of all the other for perforation of the tube two (b) (4) were reported as

MDRs in one (b)(4) the patient complained of bleeding, in the other (b)(4) the patient underwent surgery to remove the micro-insert. The five complaints listed above were the other complaints involving a perforation of the uterus or fallopian tube in which the micro-insert was located in the peritoneal cavity.

Annotation: Under Consideration
Reference: 21 CFR 803.50(a)(2)

Supporting Evidence and Relevance: I collected as part of DOC444333 copies of the firm's complaints: (b)(4) (b)(4) are all complaints of perforation with a post-procedural radiograph (HSG or CT) showing a coil in the abdominal or peritoneal cavity. The complaint records show that none of these complaints were reported as MDR. The firm has reported complaints of coils in the abdominal cavity when there is associated patient pain and a procedure to remove the coil is performed. Part of the standard for Essure in cases in which there is a failure of occlusion of the fallopian tubes is to perform another form of permanent contraception, most commonly a laparoscopic tubal ligation. In the case of (b)(4) he coil (insert) was removed during a laparoscopic tubal ligation. (b)(4) (Exhibit #13) was for a coil in the abdominal cavity. The patient complained of pain and underwent surgical removal of the coil. That complaint was classified as reportable on Jan. 6, 2011.

There is no failure mode for inserts migrating into the peritoneal cavity in the firm's latest Risk Analysis Design FMEA for ESS305 (b)(4) Exhibit #6) (See FDA 483 Observation #3) I asked Edward Yu if the firm had any safety data for an intrapertoneal location of the coil inserts. He could only provide anecdotal information for th (b)(4) I reviewed the firm's MDR list for complaints of pain and perforation treated by removal of the insert coil from the abdominal cavity there are 18 reports with the classification of complaint "perforation", 2 with "perforation and pain" and one with "perforation and bleeding" in the past 2 years. One MDR on the list is under the classification "expulsion", (b)(4) This complaint has an event description that the micro-insert was found embedded in the bowel. The data base for all complaints from Jan. 1, 2009 until Dec. 8, 2010 showed 508 complaints for perforation, 168 for micro-insert perforation and 5 for expulsion/perforation. On Jan. 6, 2011 Edward Yu gave me additional information to support the firm's position on micro-inserts in the peritoneal cavity (b)(4) pages 24, 25 (Exhibit #14), and (b)(4) pages 70 – 73 (Exhibit #15). Mr. Yu noted two examples from these studies: one of a subject who had an intra-abdominal coil for the five year duration of the study without complication; and one in which a coil was removed from the abdomen and the surgeon noted no inflammatory reaction of the surrounding tissue.

Discussion with Management: I told firm officials that my reason for considering complaints in which the micro-insert was found to be located in the peritoneal cavity, to be likely to lead to an injury is based on the number of MDR's in the firm's database in which an intra-peritoneal location led to a complication. Mr. Henry V. Bishop told me that he did not consider a micro-insert falling out of the fallopian tube because of a perforation to be a "malfunction" because it does not involve a malfunction of the micro-insert itself. I responded that because the micro-insert was designed to

remain inside the fallopian tube. The coil migrating to a different location represented the device not functioning as it was designed. Mr. Edward Yu told me that there was no evidence that the micro-insert posed a risk of injury if it was in the peritoneal cavity. Mr. Bishop mentioned the biocompatibility studies. At the close-out meeting the consensus of the firm management was that if the patient had a micro-insert in her peritoneal cavity but was asymptomatic then the complaint did not have to be reported. I said that the location of the micro-insert in the abdominal cavity was the condition that led to an intra-abdominal coil becoming symptomatic in all cases in which an intra-abdominal coil had to be removed surgically.

OBSERVATION 3

Risk analysis is incomplete.

Specifically, Design Failure Modes Effects Analysis (DFMEA) for Essure ESS305 Document Numbe[redacted] does not include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity. Since December 2007 according to complaint database provided by the firm there have been 508 complaints with the subject including perforation. 168 of these complaints were of the subject perforation (micro-insert), and 5 were expulsion/perforation. In the same time period according to the list of Medical Device Reports, there were 3 complaints reported for pain/perforation, 18 complaints for perforation and one for perforation and bleeding. In the database supplied with a complaint description I found 4 complaints of perforation from July 20, 2010 to Dec. 10, 2010 in which the micro-insert coil was found on x-ray to be in the peritoneal cavity.

Annotation: Promised to correct within 30 days
Reference: 21 CFR 820.30(g)

Supporting Evidence and Relevance: Mr. Henry V. Bishop, Quality Manager provided me with a CD-ROM labeled '[redacted]' which is a detailed database for complaints from July 20, 2010 to Dec. 10, 2010 (Exhibit #19). The complaint statistics cited in the observation were derived from this database identified on the disc as '[redacted]'. Mr. Bishop also gave me a copy of Risk Analysis Design FMEA for ESS305[redacted] (Exhibit #6). I looked at this document after figuring the number of perforation complaints and the number of complaints in which the coil was detected in the abdominal cavity. There is a reference to perforations being a possible effect of the failure mode for the coil being too stiff. Perforation itself and the possible coil in the abdominal cavity is not analyzed as a failure mode. The complaint databases that firm officials provided me with showed that from Jan. 1, 2009 until Jan. 4, 2011 there were no less than 177 complaints for perforation with the micro-insert being found in the peritoneal cavity. Review of the more detailed database (Exhibit #19) showed that that figure may not be exact because complaints could have multiple failure modes with only one listed on the less detailed database. Other than biocompatibility studies and reports from clinical trials: one of a patient who had the coil in her peritoneal cavity and was followed-up for 5 years without complications, and another of a patient who had the micro-insert removed from the abdominal cavity during a laparoscopic tubal ligation in which the physician removing the micro-insert noted that the tissue surrounding the micro-insert did not appear inflamed.

Discussion with Management: I asked Henry Bishop about the FMEA having a failure mode for micro-insert in the abdominal cavity on Dec. 21, 2010. At the close-out meeting Henry Bishop told me that he could add micro-insert in the peritoneal cavity to the FMEA. He promised to do this within 30 days of the close-out inspection.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, after failures in Design of Experiment for requalification of manufacture of microinsert coil catheters produced failing results on 11/30/2010 your firm's engineers learned from telephone conversations with engineers from your contract manufacturer that delivery wires used for the test lots were taken from quarantine without having the components fully certified Your firm did not receive the contract manufacturer's CAPA report until 12/21/2010. That CAPA did not mention the non-conformity of your contract manufacturer not following their own SOP for control of non-conforming material. Your firm covered this deviation under CAPA0014 10/25/10 opened to document actions taken to address the detachment failures noted during lot release of ESS305 as documented in

Annotation: Corrected and Verified

Reference: 21 CFR 820.100(b)

Supporting Evidence and Relevance: This inspection was initiated by the inspectional finding of the inspection of As mentioned above the failed lots were being retained at Conceptus in Mountain View, CA. Mr. Henry V. Bishop, Quality Manager, provided me with a copy of the Conceptus CAPA-0014 10/25/10 ESS305 (Exhibit #3). This CAPA was opened on 10/25/10. The issue description section (Ex. #3, page 1) refers to the noted during lot release of ESS305, as documented in (Exhibit #5, page 23). CAPA-0014 had a risk assessment (Ex. 3, page 2) for the There was no information entered for preliminary action taken, nor the root cause (Ex. 3, page 3). ESS305 Document No.: Rev. A (Exhibit #7, page 5) section 12.2 mentions the It said that a CAPA was open to establish countermeasure to avoid this issue. On 12/21/10 Mr. Bishop gave me the file for (Exhibit #4, pages 4-8). The e-mail that was attached (Ex. #4, pages 1-3) shows the request for the supplier CAPA being forwarded to The CAPA form shows electronic signatures. The Definition of the Problem was dated Dec. 3, 2010 the signature is dated 12/16/10 (Ex. #4, page 4). The containment action is entered as Ex. #4, page 4). The root cause was signed on 12/16/10 (Ex. #4, page 6). The root cause was identified as There

[redacted] The Implemented Correction was the receipt of [redacted] lots of [redacted] and training of supervisors on following protocols correctly which was performed on 12/16/10 (Ex. #4, page 11). The implementation section was signed on 12/21/10. The verification of effectiveness was entered [redacted] (Ex. #4, page 7). The method of verification was entered as [redacted] and an [redacted] There was no training for [redacted] Conceptus did not have an updated supplier CAPA until I requested it.

On Jan. 4, 2011 Henry Bishop gave me a copy of CAPA-0015 (Exhibit #18) for the [redacted] related to the [redacted] The description references [redacted] but added that [redacted] did not cover [redacted] (Ex. #18, page 1).

Because [redacted] had to be [redacted] that were supposed to be [redacted] % [redacted] I at first thought that the issue was repeated. On 12/17/2010 Mr. Bishop told me that [redacted] because a lot of [redacted] On Jan. 5, 2011 he told me that the [redacted] that caused [redacted] This was not documented in the copy of the [redacted] Summary (Exhibit #16) that he gave me on 12/17/10. On Jan. 6, 2011 he gave me a copy of the technical summary [redacted] (Exhibit #17). The root cause for the [redacted] I amended the FDA 483 to remove the reference to [redacted] and the implication that the [redacted] had the root cause at [redacted] instead of the root cause originating [redacted]

Discussion with Management: When I brought this observation to the attention of Henry V. Bishop, Quality Manager he told me that all items concerning the detachment issues with [redacted] are covered under CAPA-0014 (Exhibit #4). I said to him that CAPA-0014 did not have much information documented. It did not document the [redacted] that had been conducted and were still planned [redacted] I said that the [redacted] confirm the suspected root cause. I said that the [redacted] would have to be documented as a separate issue on the CAPA, and although it is related the actions taken and the root cause would be separate. I said that including the issues documented in [redacted] in with the CAP0014 for the [redacted] the CAPA. I also noted that [redacted] did not address [redacted] CAPA-0015 (Exhibit #18) did address [redacted] I told Mr. Bishop that I would annotate the observation as "corrected not verified" as that CAPA -0015 was opened and no corrective actions have been taken.

REFUSALS

No firm officials or personnel made any refusals to me during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

I told the firm officials that the observations are not a complete list of all the conditions that may be in violation of the Food, Drug and Cosmetic Act. I told all firm personnel present at the close-out meeting that the firm can send their reply to the District Office. I warned them that violations of the FD & C Act carry the penalties of seizure, injunction, and civil penalties.

SAMPLES COLLECTED

During this inspection I collected DOC444332, 1/5/2011 records documenting the shipment of a lot of Essure permanent contraception kit from (b) (4) nd the shipment of kits of that lot to a customer in (b) (4) also collected product labeling. Henry V. Bishop provided me with three samples of the outer packaging labeling that was available at the firm at the time form returned material and is not labeled for the same lot as the shipping records. I received an affidavit of Henry V. Bishop, identifying the records and labeling. Sample labeling do not have numbers or dates so those fields are marked with " - ".

Att.	Number	Date	Description
1		1/5/2011	Affidavit of Henry V. Bishop
2	(b) (4)		
3	(b) (4)		
4	(b) (4)		
5	(b) (4)		Transaction detail (b) (4)
6	(b) (4)		Transaction Detail (b) (4)
7	(b) (4)	(b) (4)	Invoice
8	(b) (4)		(b) (4)
9	(b) (4)		Invoice for (b) (4)
10	-	-	External Product Packaging (from ret. prod. of diff. lot#)
11	-	-	Catheter pouch (3 collected)
12	-	-	Catheter card with printed on label (3 collected)
13	-	-	Patient ID cards (3 items collected)
14	-	-	Instructions for Use (3 collected)

I also collected DOC444333, 1/6/2011 which includes printouts of complaint reports from the firm's complaint handling database, with an affidavit of Edward C. Yu identifying the records.

Att.	Number	Incident date	Description
1	-	1/6/2011	Affidavit of Edward C. Yu
2	(b) (4)	11/3/2010	Complaint: scope perforated bowel
3	(b) (4)	11/16/2010	Complaint: graspers perforated bowel
4	(b) (4)	10/01/2010	Complaint: coil in peritoneal cavity
5	(b) (4)	10/05/2010	Complaint: coil in peritoneal cavity
6	(b) (4)	5/11/2010	Complaint: coil in peritoneal cavity
7	(b) (4)	10/26/2010	Complaint: coil in peritoneal cavity
8	(b) (4)	11/5/2010	Complaint: Pain; coil in peritoneal cavity
9	(b) (4)	9/1/2010	Complaint: coil in peritoneal cavity

VOLUNTARY CORRECTIONS

On Jan. 4, 2011 Henry V. Bishop, Director Quality, gave me a copy of CAPA-0015 (Exhibit #18) for the (b) (4) This addressed the previously observed lack of a corrective action along with the supplier corrective action not addressing as a root cause (b) (4) On Jan. 6, 2011 Edward C. Yu, Vice President Clinical Research and Regulatory Affairs told me that Conceptus had reclassified complaint (b) (4) as MDR-reportable.

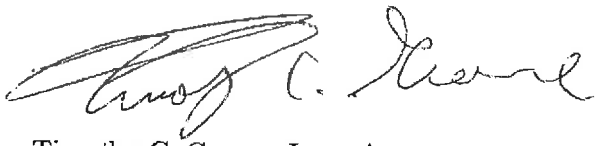
EXHIBITS COLLECTED

1. Corrective and Preventive Actions (CAPA) SOP-00935 Rev. U (13 pages)
2. Product Return, Complaint Handling, and Reporting SOP-1630 Rev. AC (5 pages)
3. CAPA-0014 10/25/10 (b) (4) ESS305 (5 pages)
4. (b) (4) with additional information in a printout of e-mails between Conceptus an (b) (4) (11 pages)
5. (b) (4) 3/26/10 (71 pages)
6. Risk Analysis Design FMEA for ESS305 (b) (4) 14 oversized pages)
7. (b) (4) Corrective Action Request (b) (4) 2/2/2010 (2 pages)
8. (b) (4) for Conceptus Essure ESS305 Document No. (b) (4) 10 pages)
9. Inventory Detail by Location (2 pages)
10. Work Instruction WI-03303 Medical Device Vigilance (MDV) Reporting (8 pages)

11. Work Instruction WI-03306 MDR Processing (8 pages)
12. Product Recall Procedure SOP 01045 Rev. H 1/18/08 9 (11 pages)
13. Complaint file (b) (4) file updated as of Jan. 5, 2011 (8 pages)
14. Report of (b) (4) pages 24, 25 (2 pages)
15. Report of (b) (4) pages 70 – 73 (4 pages)
16. (b) (4) Summary (5 pages)
17. (b) (4) Technical Report (6 pages)
18. CAPA-0015 12/21/10 use of (b) (4) (3 pages)
19. CD-ROM '(b) (4) detailed complaint database from July 20, 2010 to Dec. 10, 2010. (1 Disc sealed on 1/18/2011 in a "jewel case")

ATTACHMENTS

1. FDA 482, dated Dec. 8, 2010
2. FDA 482, dated Jan. 4, 2011
3. FDA 483, dated Jan. 6, 2011
4. FDA 483, dated Jan. 6, 2011 (amended)
5. E-mail exchange between CSO Timothy C. Grome and Brenda S. Lucas CDRH OSB, from Dec. 22, 2010 to 1/4/2011 and e-mail from Brenda Lucas on 1/21/2011. (7 pages)



Timothy C. Grome, Investigator